

G. Considered Cumulatively, the Evidence Overwhelmingly Demonstrates that Cigarettes and Smokeless Tobacco Are Intended to Affect the Structure and Function of the Body

As summarized above, the evidence in the record provides several independent bases for the Agency's finding that cigarettes and smokeless tobacco are "intended" to affect the structure and function of the body. Independently, each of these distinct categories of evidence is a strong and sufficient basis for the Agency's conclusion that the manufacturers of cigarettes and smokeless tobacco intend the pharmacological effects and uses of their products. Considered together, they are mutually corroborating. Both independently and taken as a whole, therefore, the evidence in the administrative record overwhelmingly establishes that cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body" within the meaning of the Act.

III. Cigarettes and Smokeless Tobacco Are Combination Products Consisting of "Drug" and "Device" Components

The Agency's findings in sections I and II establish that the nicotine in cigarettes and smokeless tobacco is a "drug" under section 201(g)(1)(C) of the Act. These findings show that the nicotine in cigarettes and smokeless tobacco "affect[s] the structure or any function of the body" and that these effects are "intended." These findings thus demonstrate that the nicotine in cigarettes and smokeless tobacco meets the statutory definition of a "drug."

Cigarettes and smokeless tobacco are not simply packaged nicotine, however. They also include delivery devices that deliver nicotine to the body. Section 201(h)(3), 21 U.S.C. 321(h)(3). In the case of cigarettes, the device components work together upon combustion outside the body to form a nicotine-containing aerosol, which then delivers

nicotine to the body when inhaled by the smoker. In the case of smokeless tobacco, the device components function by presenting nicotine to the consumer in a form that is palatable and absorbable by the buccal mucosa. Unlike the drug nicotine, these device components achieve their primary intended purpose without chemical action in or on the body and without being metabolized.

The presence of both drug and device components in cigarettes and smokeless tobacco make these products “combination products” under section 503(g) the Act, 21 U.S.C. 353(g)(1).

IV. FDA’s Assertion of Jurisdiction Over Cigarettes and Smokeless Tobacco at This Time Is Justified

FDA has always exercised jurisdiction over tobacco products when there is sufficient evidence in the record to establish that these products are “intended” to treat or prevent disease or to affect the structure or function of the body. Over thirty years ago, for instance, the Agency asserted jurisdiction over a brand of cigarettes when the evidence established that the brand was intended to reduce body weight. *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959).

The Agency last considered whether to regulate cigarettes in the late 1970’s, when the Agency rejected petitions by Action on Smoking and Health (ASH) urging the Agency to regulate cigarettes as drugs or devices. The Agency agreed with ASH that “objective evidence other than manufacturers’ claims can be material to a determination of intended use” and that “evidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act.” However, the Agency concluded that the evidence presented by ASH in the

petition was insufficient to establish that cigarettes and smokeless tobacco were in fact intended to affect the structure and function of the body. The court deferred to the Agency's determination not to regulate cigarettes as drugs but expressly left open the possibility that FDA might, at a later date, revisit its decision and determine that it did indeed have jurisdiction over cigarettes. *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

The evidence regarding the intended use of cigarettes and smokeless tobacco has changed dramatically since *ASH*. First, a scientific consensus has emerged since 1980 that nicotine is addictive and has other significant pharmacological effects and that cigarettes and smokeless tobacco are used by consumers to obtain pharmacological effects. As summarized above, no major public health organization had determined that nicotine was an addictive drug before 1980. Between 1980 and 1994, however, every leading scientific organization with expertise in addiction concluded that nicotine is addictive. This new evidence thus shows that the pharmacological effects and uses of cigarettes and smokeless tobacco have become foreseeable.

Second, scientific evidence accumulated since 1980 has shown that the vast majority of people who use cigarettes and smokeless tobacco use these products to satisfy addiction or to obtain other pharmacological effects. As summarized above, this new evidence now shows that 77% to 92% of smokers are addicted to nicotine and provides a basis for estimating that 75% of young regular smokeless tobacco users are addicted to nicotine. This new evidence establishes that consumers use cigarettes and smokeless tobacco predominantly for pharmacological purposes.

Third, FDA, congressional, and other investigations have recently uncovered a wealth of documents from a wide range of tobacco companies that show that the manufacturers have long known of the pharmacological effects and uses of nicotine and have designed their products to provide pharmacologically active doses of nicotine to consumers. Virtually none of this information was available to FDA in 1980.

Information developed since 1980 also demonstrates that the Agency has a unique public health opportunity to reduce substantially the more than 400,000 deaths from tobacco use each year in the United States. This information shows that for most people tobacco use and nicotine addiction begin in childhood and adolescence, and that an increasing number of American children and adolescents are using cigarettes and smokeless tobacco. The data now suggest that if children and adolescents can be prevented from initiating tobacco use during their teenage years, they are unlikely to begin tobacco use later in life, thereby preventing the onset of tobacco-related disease and premature death.

Before the importance of youth-centered interventions was identified, most of the regulatory approaches available under the Federal Food, Drug, and Cosmetic Act to address tobacco-related disease and death, such as removal of the products from the market, were not believed to be feasible solutions. It is now apparent, however, that FDA's authority to restrict the sale, distribution, and use of cigarettes and smokeless tobacco to people under the age of eighteen is an effective tool to reduce the adverse health consequences of tobacco use. Thus, asserting jurisdiction over cigarettes and

smokeless tobacco now presents an opportunity to use the Agency's resources effectively for substantial public health gains.

The court in *ASH* specifically recognized that FDA was permitted to modify its position and that any new FDA position would be accorded deference by the courts. *Id.* at 242 n.10. In light of the substantial new information, FDA has reviewed its earlier determination not to assert jurisdiction over tobacco products. The new evidence persuades the Agency to conclude that its previous position is no longer consistent with the relevant facts and should be changed. The evidence before the Agency is now sufficient to establish that cigarettes and smokeless tobacco are in fact intended to affect the structure and function of the body.

V. *Congress Has Not Precluded or Preempted FDA from Regulating Cigarettes and Smokeless Tobacco*

FDA disagrees with the comments of the tobacco industry that assert that Congress has precluded or preempted FDA from regulating cigarettes and smokeless tobacco. The plain language of the Act does not exclude cigarettes or smokeless tobacco from FDA jurisdiction. Tobacco products are expressly excluded from the jurisdiction of the Consumer Product Safety Commission under the Federal Hazardous Substances Act and from the jurisdiction of the Environmental Protection Agency under the Toxic Substances Control Act. The absence of any similar exclusion in the Federal Food, Drug, and Cosmetic Act demonstrates that Congress has not chosen to exclude cigarettes and smokeless tobacco from FDA jurisdiction.

The legislative history of the Act confirms that the Act should not be interpreted to preclude FDA jurisdiction over tobacco products. Congress has long known that FDA

will assert jurisdiction over cigarettes when the evidence establishes that the cigarettes are intended to affect the structure or function of the body. For instance, FDA asserted jurisdiction more than 30 years ago over cigarettes that were intended to reduce weight. This demonstrates that Congress has not “ratified” or “acquiesced in” an interpretation of the Act that would preclude FDA from regulating tobacco products intended to affect the structure or function of the body.

Moreover, even if Congress had acquiesced in such an interpretation of the Act, congressional acquiescence in a prior agency interpretation does not prevent an agency from changing its interpretation. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 45 (1983). In the case of cigarettes and smokeless tobacco, a change in interpretation would be justified by the new evidence in the record—evidence never previously before either the Agency or Congress.

The Agency also disagrees that other federal statutes preempt FDA jurisdiction over cigarettes and smokeless tobacco. Both the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act have provisions that expressly specify the limited extent to which these laws preempt FDA and other federal agencies from regulating cigarettes or smokeless tobacco. In the Federal Cigarette Labeling and Advertising Act, for instance, federal agencies are preempted only from requiring “statement[s] relating to smoking and health . . . on any cigarette package.” 15 U.S.C. 1334(a). The narrow preemption provisions that Congress expressly included in these statutes do not apply to FDA’s assertion of jurisdiction over cigarettes and smokeless tobacco.

No other federal statutes contain provisions preempting FDA regulation of tobacco products. In the absence of an express preemption provision, one federal statute preempts another federal statute only where there is an irreconcilable conflict between the two laws. *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253 (1992). There is no irreconcilable conflict between FDA jurisdiction and other federal statutes.

VI. *FDA Employed Procedures That Provided an Opportunity for Full Public Participation and Exceeded All Legal Requirements*

FDA went to great lengths to involve the public in the process by which the Agency made its final jurisdictional determination. The Commissioner made public his intention to investigate the role of nicotine in tobacco products, testified twice before Congress on the Agency's findings, wrote to all the major cigarette and tobacco companies requesting information on the role of nicotine in their products, and held a public advisory committee meeting on the abuse potential of nicotine. Although the Agency is not required to undertake rulemaking to establish jurisdiction over new products, the Agency published in the *Federal Register* its initial jurisdictional findings and comprehensive legal analysis in a 325-page document, supported by over 600 footnotes, and sought public comment on those findings. The Agency placed over 210,000 pages of supporting documents in a public docket. FDA received over 700,000 comments on the Jurisdictional Analysis and the accompanying proposed rule. The Agency has responded to substantive comments in this Annex and in the preamble to the Final Rule.

FDA disagrees with the comments of the tobacco industry that the record supporting the Jurisdictional Analysis or the procedures the Agency followed were inadequate. The procedures the Agency employed in reaching its final determination

exceeded the requirements of the Administrative Procedures Act (APA) and the Agency's own procedural requirements.

INTRODUCTION

On August 11, 1995, the Food and Drug Administration (hereinafter FDA or the Agency) announced the results of its extensive investigation and comprehensive legal analysis regarding the Agency's jurisdiction over cigarettes and smokeless tobacco in a document entitled, "Nicotine in Cigarettes and Smokeless Tobacco Products Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as the "Jurisdictional Analysis"). 60 FR 41453-41787 (Aug. 11, 1995). The Agency reported that its investigation and analysis supported a finding at that time that nicotine in cigarettes and smokeless tobacco is a drug and that these products are drug delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act (hereinafter the Act). Because of the unique importance of the jurisdictional issue, the Agency invited comment on this finding.

The public comment period closed on January 2, 1996. 60 FR 53620 (Oct. 16, 1995). On March 20, 1996, the Agency published in the *Federal Register* notice of an additional 30 day comment period, until April 19, 1996, limited to specific documents the Agency added to the docket in support of the Agency's analysis of jurisdiction. 61 FR 11419 (Mar. 20, 1996). The Agency received over 700,000 comments on its Jurisdictional Analysis and its Proposed Rule restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. The Agency has carefully considered these comments.

This final jurisdictional determination responds to the public comments and reports the Agency's conclusion that the nicotine in cigarettes and smokeless tobacco is a drug and that cigarettes and smokeless tobacco are drug delivery devices whose purpose is to

deliver nicotine to the body in a manner in which it can be readily absorbed. These products, therefore, are subject to FDA regulation under the Act.

The legal question of whether cigarettes and smokeless tobacco are drugs and devices subject to FDA regulation is one that “FDA has jurisdiction to decide with administrative finality.” *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973). The Act defines a “drug” as (1) an article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” or (2) an article (other than food) “*intended to affect the structure or any function of the body of man or other animals.*” Section 201(g)(1)(B) and (C), 21 U.S.C. 321(g)(1)(B) and (C) (emphasis added). The Act’s device definition parallels the drug definition and provides that an instrument, apparatus, or other similar article is a “device” if it is (1) “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” or (2) “*intended to affect the structure or any function of the body of man or other animals.*” Section 201(h)(2) and (3), 21 U.S.C. 321(h)(2) and (3) (emphasis added). These definitions are intended to be broad in scope and to encompass products that are not within the ordinary medical definitions of drugs and devices. *See United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793 (1969) (“we think it plain that Congress intended to define ‘drug’ far more broadly than does the medical profession”).

In applying these legal standards to cigarettes and smokeless tobacco, the Agency has focused on the second prong of the definition of drug and device: whether cigarettes and smokeless tobacco are “intended to affect the structure or any function of the body.” Historically, the Agency has regulated tobacco products whenever the evidence before the